JAN 13 2012 K113490

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 22, 2011
Submitter:	GE Healthcare (GE Medical Systems, LLC) 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact Person:	Robin Martin Regulatory Affairs Leader GE Healthcare (GE Medical Systems, LLC) Ph: (262) 312-1120 Fax: (262) 364-2785
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare (GE Medical Systems, LLC) Ph: (262) 521-6848 Fax: (262) 364-2785
Device: Trade Name:	Optima MR450w
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	892.1000
Product Code:	LNH
Predicate Device(s):	Optima MR450w (K091536)
Device Description:	The 1.5T GE Optima MR450w features a superconducting magnet operating at 1.5 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Optima MR450w is proposed to be marketed with an added XP Gradient configuration compatible with systems that have the GEM Coil Suite option. The 1.5T GE Optima MR450w is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).

Intended Use:

The Optima™ MR450w is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Optima™ MR450w reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology:

The Optima MR450w employs the same fundamental scientific technology as its predicate device, the Optima MR450w. Refer to Section 12 for details of the System, Technical and Application Comparison Charts.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Optima MR450w and its applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing:
  - Signal-to-noise ratio (SNR)
  - Geometric distortion
  - Image uniformity
  - Slice thickness
  - Spatial resolution
- Component, Subsystem and System Testing (Verification)
- Simulated use testing (Validation)

In accordance with voluntary standards identified in Section 9 and FDA's November 14, 1998 guidance entitled 'Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices', the following safety tests were completed:

- Safety Testing
  - Static Field Strength
  - Acoustic noise
  - DB/dt
  - RF heating (SAR)
  - Biocompatibility

Summary of Clinical Tests:

The subject of this premarket submission, Optima MR450w did not require external clinical studies to support substantial equivalence. Internal scans for workflow and image quality data were used for clinical validation.

Conclusion:

GE Healthcare considers the Optima MR450w to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Robin Martin
Regulatory Affairs Leader
GE Medical Systems, LLC.
3200 N. Grandview Blvd.
WAUKESHA WI 53188

JAN 13 2012

Re: K113490
Trade/Device Name: Optima MR450w
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 22, 2011
Received: November 25, 2011

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

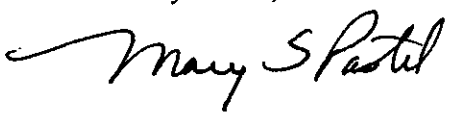
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 113490

Device Name: Optima MR450w

Indications for Use:

The Optima™ MR450w is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used.

The images produced by the Optima™ MR450w reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K113490